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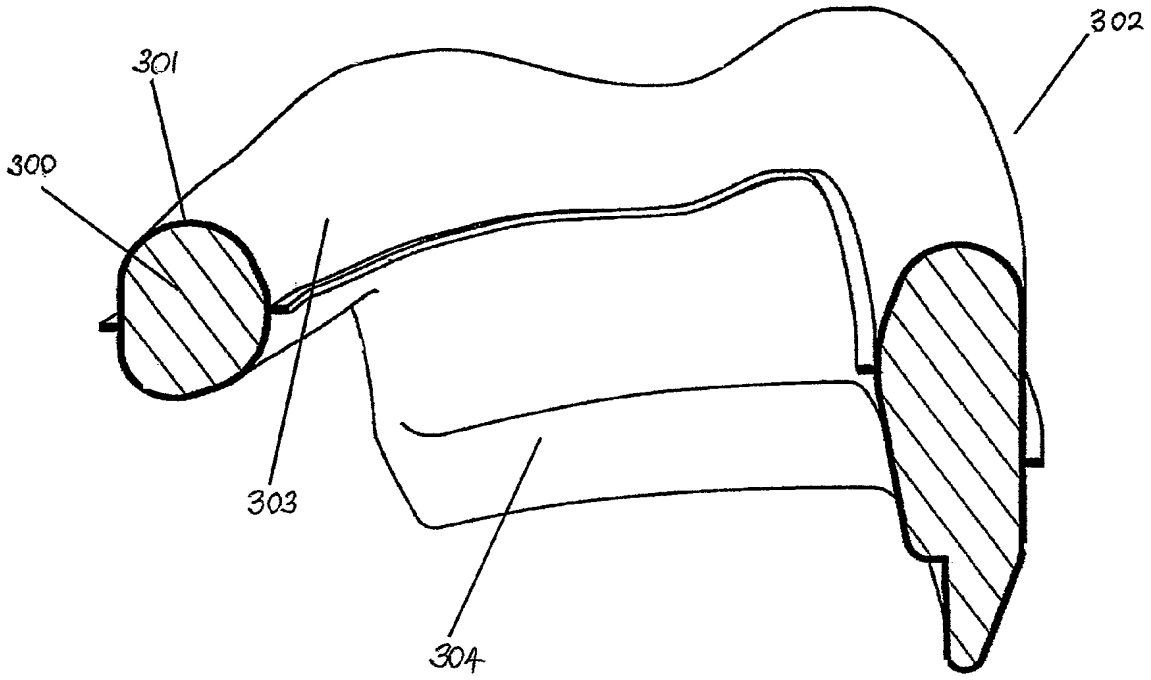
(54) Title: BREATHING ASSISTANCE APPARATUS



(57) Abstract: A mask with cushion that has an outer film is disclosed. The film may be self-skinning or a film formed about or glued to the cushion body. In another form the cushion may be formed with at least a portion having a plurality of adjacent voids having a honeycomb-like structure.

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"BREATHING ASSISTANCE APPARATUS"

FIELD OF INVENTION

This invention relates to patient interfaces particularly though not solely for use in delivering CPAP therapy to patients suffering from obstructive sleep apnoea (OSA). In particular, this invention relates to cushions used to support and seal the mask to a patient's face.

BACKGROUND OF THE INVENTION

In the art of respiration devices, there are well known variety of respiratory masks which cover the nose and/or mouth of a human patient in order to provide a continuous seal around the nasal and/or oral areas of the face such that gas may be provided at positive pressure within the mask for consumption by the patient. The uses for such masks range from high altitude breathing (i.e., aviation applications) to mining and fire fighting applications, to various medical diagnostic and therapeutic applications.

One requisite of such respiratory masks has been that they provide an effective seal against the patient's face to prevent leakage of the gas being supplied. Commonly, in prior mask configurations, a good mask-to-face seal has been attained in many instances only with considerable discomfort for the patient. This problem is most crucial in those applications, especially medical applications, which require the patient to wear such a mask continuously for hours or perhaps even days. In such situations, the patient will not tolerate the mask for long durations and optimum therapeutic or diagnostic objectives thus will not be achieved, or will be achieved with great difficulty and considerable patient discomfort.

US Patent No. 5,243,971 and US Patent No. 6,112,746 are examples of prior art attempts to improve the mask system US Patent No. 5,570,689 and PCT publication No. WO 00/78384 are examples of attempts to improve the forehead rest.

US6,634,358 and US6,581,602 of ResMed Limited disclose a nasal mask cushion to sealingly connect a mask to a wearer's face. The cushion has a nose-receiving cavity bounded by a frame and membrane. The membrane is spaced away from the rim of the frame, and its outer surface is of substantially the same shape as the rim.

In the prior art mask cushions are provided that have a solid inner wall that provides support but doesn't allow much change in the shape of the cushion. Thus, such mask cushions can be uncomfortable for a user. Furthermore, often prior art mask cushions are made of foam which is neither waterproof nor durable.

SUMMARY OF THE INVENTION

It is an object of the present invention to attempt to provide a patient interface which goes some way to overcoming the abovementioned disadvantages in the prior art or which will at least provide the industry with a useful choice.

Accordingly in a first aspect the present invention consists in a cushion for a patient interface adapted to supply gas to a patient comprising:

a cushion body; and

an outer cover,

wherein said body and cover are substantially formed of the same elemental material.

Preferably said elemental material is polyurethane.

Preferably said cushion body is formed in polyurethane foam.

Preferably said outer cover is formed in polyurethane film.

Preferably said outer cover is adhered to said body.

Preferably said cushion body is assembled from more than one moulded component.

Preferably said cushion body includes an attachment adapted to engage a mask.

In a second aspect the present invention consists in a cushion for a patient interface adapted to supply gas to a patient comprising:

a cushion body having an outer cover, and

an outer sealing sheath,

wherein said cushion body is detachable from said outer sheath and said patient interface.

Preferably said cushion body and said outer sealing sheath are formed of the same elemental material.

Preferably said elemental material is silicone.

In a third aspect the present invention consists in a mask adapted to deliver gas to a patient comprising:

a cushion body wherein at least a portion thereof has a plurality of adjacent voids.

Preferably each of said voids has a hexagonal cross section.

Preferably each of said voids has an oval, square, rectangular, or other shaped cross section.

Preferably said cushion body has an outer cover and said mask further includes an outer sealing sheath.

BRIEF DESCRIPTION OF THE DRAWINGS

Preferred forms of the present invention will now be described with reference to the accompanying drawings.

Figure 1 is a block diagram of a humidified continuous positive airway pressure system as might be used in conjunction with the present invention.

Figure 2 is an illustration of a nasal mask in use with a cushion according to the preferred embodiment of the present invention.

Figure 3 shows a perspective view of the mask with cushion.

Figure 4 is a cutaway view of the mask showing the cushion.

Figure 5 shows a cross section of second preferred embodiment of the mask cushion.

Figure 6 shows perspective view of an inner cushion of the second preferred embodiment of the mask cushion.

Figure 7 shows a cross section of an inner cushion with a reinforcement film or coating.

Figure 8 shows a cross section of an inner cushion made up of two portions welded or glued in the middle.

Figure 9 shows a cross section of an inner cushion with a connecting catch between the halved portions of the cushion.

Figure 10 shows a cross section of a halved foam cushion with mounting brackets.

Figure 11 shows a plan view of a mask cushion having a honeycomb-like structure.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

The present invention provides improvements in the delivery of CPAP therapy. In particular a patient interface and cushion is described which is quieter for the patient to wear and reduces leakage from the mask, therefore providing for a good seal on a wearer's nose and face. Furthermore, the patient interface and cushion of the present invention provides for conformity to a patient's facial contours unlike other solid silicone mask or cushion designs and is comfortable for a patient to wear. Also, the cushion of the present invention is durable and allows the pressure of the face of a user to be reduced preventing face sores and the like.

It will be appreciated that the patient interface as described in the preferred embodiment of the present invention can be used in respiratory care generally or with a ventilator but will now be described below with reference to use in a humidified CPAP system.

It will also be appreciated that the present invention can be applied to any form of patient interface including, but not limited to, nasal masks, oral masks and mouthpieces.

With reference to Figure 1 a humidified Continuous Positive Airway Pressure (CPAP) system is shown in which a patient 1 is receiving humidified and pressurised gases through a patient interface 2 connected to a humidified gases transportation pathway or inspiratory conduit 3. It should be understood that delivery systems could also be VPAP (Variable Positive Airway Pressure) and BiPAP (Bi-level Positive Airway Pressure) or numerous other forms of respiratory therapy. Inspiratory conduit 3 is connected to the outlet 4 of a humidification chamber 5 which contains a volume of water 6. Inspiratory conduit 3 may contain heating means or heater wires (not shown) which heat the walls of the conduit to reduce condensation of humidified gases within the conduit. Humidification chamber 6 is preferably formed from a plastics material and may have a highly heat conductive base (for example an aluminium base) which is in direct contact with a heater plate 7 of humidifier 8. Humidifier 8 is provided with control means or electronic controller 9 which may comprise a microprocessor based controller executing computer software commands stored in associated memory.

Controller 9 receives input from sources such as patient input means or dial 10 through which a patient of the device may, for example, set a predetermined required value (preset value) of humidity or temperature of the gases supplied to patient 1. The controller may also receive input from other sources, for example temperature and/or flow velocity sensors 11 and 12 through connector 13 and heater plate temperature sensor 14. In response to the patient set humidity or temperature value input via dial 10 and the other inputs, controller 9 determines when (or to what level) to energise heater plate 7 to heat the water 6 within humidification chamber 5. As the volume of water 6 within humidification chamber 5 is heated, water vapour begins to fill the volume of the chamber above the water's surface. The water vapour is then passed out of the humidification chamber 5 outlet 4 with the flow of gases (for example air) provided from a gases supply means or blower 15 which enters the chamber through inlet 16. Exhaled gases from the patient's mouth are passed directly to ambient surroundings in Figure 1.

Blower 15 is provided with variable pressure regulating means or variable speed fan 21 which draws air or other gases through blower inlet 17. The speed of variable speed fan 21 is controlled by electronic controller 18 (or alternatively the function of controller 18 could be

carried out by controller 9) in response to inputs from controller 9 and a patient set predetermined required value (preset value) of pressure or fan speed via dial 19.

Nasal Mask

According to a first embodiment of the present invention the patient interface is shown in Figure 2 as a nasal mask. The mask includes a hollow body 100 with an inlet 101 connected to the inspiratory conduit 3. The mask 2 is positioned around the nose of the patient 1 with the headgear 103 secured around the back of the head of the patient 1. The headgear 103 preferably attaches to a gliding strap or straps 117 by way of connectors 118. The gliding straps 117 allow for the patient to move his head but the mask 2 and more particularly the cushion 104 is not pulled from the patient's face. The restraining force from the headgear 103 on the hollow body 100 and the forehead rest 105 ensures enough compressive force on the mask cushion 104, to provide an effective seal against the patient's face.

The hollow body 100 is constructed of a relatively inflexible material for example, polycarbonate plastic. Such a material would provide the requisite rigidity as well as being transparent and a relatively good insulator. The expiratory gases can be expelled through a valve (not shown) in the mask, a further expiratory conduit (not shown), or any other such method as is known in the art.

Mask Cushion

Referring now to Figures 3 and 4 in particular, the mask cushion 104 is shown in further detail. The cushion 104 is provided around the periphery of the nasal mask hollow body 100 to provide an effective seal onto the face of the patient to prevent leakage. The mask cushion 104 is shaped to approximately follow the contours of a patient's face. The mask cushion 104 will deform when pressure is applied by the headgear (108, see Figure 2) to adapt to the individual contours of any particular patient. In particular, there is an indented section 106 that fits over the bridge of the patient's nose as well as a less indented section 107 to seal around the section beneath the nose and above the upper lip.

As shown in Figure 4 the mask cushion 104 is composed of an inner cushion 108 covered by an outer sealing sheath 109. The inner cushion 108 is constructed of a resilient material for example, polyurethane foam, to enable distribution of pressure evenly along the seal around the patient's face. The inner cushion 108 is located around the outer periphery 110 of the open face 111 of the hollow body 100. Similarly the outer sheath 109 may be

commonly attached at its base 112 to the periphery 110 and loosely covers over the top of the inner cushion 108.

In a first embodiment of the mask cushion shown in Figure 4 the bottom of the inner cushion 108 fits into a generally triangular cavity 113 in the hollow body 100. The cavity 113 is formed from a flange 114 running mid-way around the interior of the hollow body 100. The outer sheath 109 fits in place over the cushion 108, holding it in place. The sheath 109 is secured by a snap-fit to the periphery 110 of the hollow body. The periphery 110 of the hollow body is shown including an outer bead 115. The sheath 109 includes a matching bead 116, whereby once it is stretched around the periphery 110, the two beads 115, 116 engage to hold the sheath 109 in place.

Referring now to Figures 5 and 6, a second embodiment of the mask cushion of the present invention is depicted. In this second embodiment, the inner cushion 200 includes a raised bridge 201 in the nasal bridge region. Thus the notch in the contacting portion is less pronounced than proceeding embodiments, however as the raised bridge 201 is unsupported it is much more flexible and results in less pressure on the nasal bridge of the patient. The outer sheath 202 contacts the cushion 200 throughout the raised bridge 201.

Referring particularly to Figure 6, the foam cushion 200 includes a check contour 203, which follows the cartilage extending from the middle of the nose, and a contoured lip sealing portion 204, to seal between the base of the nose and the upper lip.

Honeycomb Cushion

Referring to Figure 11, a third embodiment of the mask cushion of the present invention is illustrated. The inner cushion 400 may be formed in a honeycomb structure 401. The cushion 400 is shown in Figure 11 with a partial area of an array of hexagonal areas or voids 401. It must be noted that select parts of the cushion could be made in the honeycomb structure, while other areas are fully formed from foam, gel, silicon, rubber or the like material. In yet other forms, the whole cushion may be formed in this type of honeycomb-like structure.

This type of honeycomb-like structure of the cushion 400 reduces the pressure on the patient's nasal bridge region in use, meaning this cushion 400 is more comfortable to use.

The hexagonal cushion 400 is preferably formed in a silicon or rubber material and as such is likely to be more flexible, durable and hygienic. The cushion 400 is preferably formed by injection moulding in silicone. Therefore, a mould for use to mould the cushion will have hexagonal or other appropriately shaped uprights that form the voids in the cushion.

The hexagonal cushion 400 may also be coated with an outer film or coating (not shown) by similar methods as are described below. In particular, the outer coating may be formed from silicone.

Film or Coating

A reinforcement film or coating (outer cover) can be applied onto any of the above described inner cushion's outer surfaces to reduce the possibility of tearing of the inner cushion. Such a reinforcement film would likely be made of a resilient material for example polyurethane. The coating may be applied onto the cushions surface using a variety of methods, for example, injection of a foam cushion onto the pre-made film that lines the cushion mould or adhering a pre-made cushion with a plastic film using processes such as high frequency welding, ultrasonic welding, or gluing. The film or coating could be a plastic film, for example a durable polyurethane film, or a sprayed or painted on plastic or paint coating. Alternatively, the inner cushion may be dipped in a plastic or paint to coat it.

It is preferred that the mask cushion in this form be comprised of an inner cushion with an outer cover and an outer sealing sheath. Preferably the inner cushion and outer cover are formed of the same elemental material, for example, polyurethane foam and film, respectively. The outer sealing sheath is preferably made of a flexible material, such as silicone or rubber. In other forms the inner cushion may be made of a gel, silicone, or rubber like material. In this form the inner cushion is not attached to the mask but floats between the outer sealing sheath and mask body. This enables the inner cushion, whether made from a foam or gel, silicone or rubber-like material and can be removed, enabling easy cleaning or the use of different sized inner cushions with the mask for better custom fitting for the user.

Referring to Figure 7, a cushion 300 with a reinforcement film 301 is illustrated as a whole cushion body 302. The cushion body 302 includes an upper outer periphery portion 303 and lower hollow fitting portion 304. The outer periphery portion 3 rests against the patient's face in use and the hollow fitting portion 304 attaches to the mask hollow body, for example, 100 in Figure 4 in a manner as described above.

Referring to Figure 7, the reinforcement film or coating 301 for example, a plastic film, can be applied to the outer periphery portion 303 and hollow fitting potion 304 separately, usually by injection moulding each portion, although other suitable methods such as painting or spraying may be used. Later the two portions may be joined together to form the whole cushion 300. These two portions 303, 304 can be joined using different methods; one example

is by high frequency welding where high or ultrasonic frequencies cause the cushion material, for example, foam (in the preferred embodiment), to meld together. The advantage of moulding two portions and joining them to make up the cushion is that the cushion is easier to manufacture.

As an example, the two portions 303, 304 of the cushion 300 may be formed by injecting foam into female moulds, then removing these and covering them with a plastic coating then using high or ultrasonic welding to meld the two portions plastic coatings together.

In other forms the cushion 300 may be welded on to the mask hollow body 100. In this form the cushion would be permanently attached to the mask body 100 (see Figure 4). Here, it is likely that the mask body 100 is made from an injection moulding grade thermoplastic. A film 301 can be applied on to the pre-made portions 303, 304 or whole cushion 300 itself. For example, the reinforcement film or coating may be applied on to the pre-made cushion 300 by means of spraying (using an air-gun or the like), dipping or painting (of the mould before injecting of the cushion). Again, the cushion could be made in a single mould or in portions as described above.

In another form the film may be made of durable polyurethane and be vacuum formed onto a female mould, the mould may be a single cavity or multi-cavity to enable multiple forming of upper and lower portions of the cushion. The material making up the cushion, may then be injected into the cavity onto the film. The cushion and film are then left to cure at a temperature between 40°C and 50°C for 5 to 8 minutes. During this time the material making up the cushion (preferably foam) adheres to the film. The end result is a cushion covered with a plastic coating that will be resistant to wear, tear and moisture.

Figure 8, shows a cross section of a cushion 500 made up of two portions 501, 502 that are each covered in a coating or film 503 (similar to those described above) that have been welded together where the portions 501, 502 meet.

Referring to Figure 9, the halved portions 601, 602 of a cushion 600 may be formed with a catch or key 604. The two parts of the catch 604 are keyed together to assist in the alignment of the portions 601, 602 and then the portions are welded together. Each of the portions 601, 602 is shown in Figure 9 as being covered by a coating or film 603. The catch of key 604 has the purpose of assisting to align the two portions and to prevent movement of the two portions during welding.

Referring to Figure 10, a cushion 700 may be attached to the mask body with a mounting bracket 701 that clips to a groove (not shown) in the hollow mask body. The cushion 703, for example, moulded of foam, is preferably directly molded on the bracket 701. The reinforcement film or coating 702 is then adhered to the cushion's surface using the methods described above, an adhesive material or high frequency or ultrasonic welding.

In alternative forms of the cushion the cushion could be moulded onto the film and then welded to the bracket. The bracket is preferably made from a polyurethane or thermoplastic and has the purpose of enabling the clipping of the cushion to the mask body.

A mask cushion with a film coating will mean that while the cushion remains flexible and soft, it is more durable. Furthermore, the cushion will be waterproof, as moisture from the patient's skin or caused by surrounding apparatus or therapy the patient is undergoing, is not absorbed by the cushion. Therefore, the cushion will also be more hygienic.

WE CLAIM:

1. A cushion for a patient interface adapted to supply gas to a patient comprising:
a cushion body; and
an outer cover,
wherein said body and cover are substantially formed of the same elemental material.

2. A cushion as claimed in claim 1 wherein said elemental material is polyurethane.

3. A cushion as claimed in claim 1 or 2 wherein said cushion body is formed in polyurethane foam.

4. A cushion as claimed in claim 1 to 3 wherein said outer cover is formed in polyurethane film.

5. A cushion as claimed in claim 1 to 4 wherein said outer cover is adhered to said body.

6. A cushion as claimed in claim 1 to 5 wherein said cushion body is assembled from more than one moulded component.

7. A cushion as claimed in claim 1 to 6 wherein said cushion body includes an attachment adapted to engage a mask.

8. A cushion for a patient interface adapted to supply gas to a patient comprising:
a cushion body having an outer cover, and
an outer sealing sheath,
wherein said cushion body is detachable from said outer sheath and said patient interface.

9. A cushion as claimed in claim 8 wherein said cushion body and said outer sealing sheath are formed of the same elemental material.

10. A cushion as claimed in claim 9 wherein said elemental material is silicone.

11. A mask adapted to deliver gas to a patient comprising:
a cushion body wherein at least a portion thereof has a plurality of adjacent voids.

12. A mask as claimed in claim 11 wherein each of said voids has a hexagonal cross section.

13. A mask as claimed in claim 11 wherein each of said voids has an oval, square, rectangular, or other shaped cross section.

14. A mask as claimed in claim 11 wherein said cushion body has an outer cover and said mask further includes an outer sealing sheath.

15. A cushion for a patient interface as herein described with reference to the accompanying figures.

16. A mask as herein described with reference to the accompanying figures.

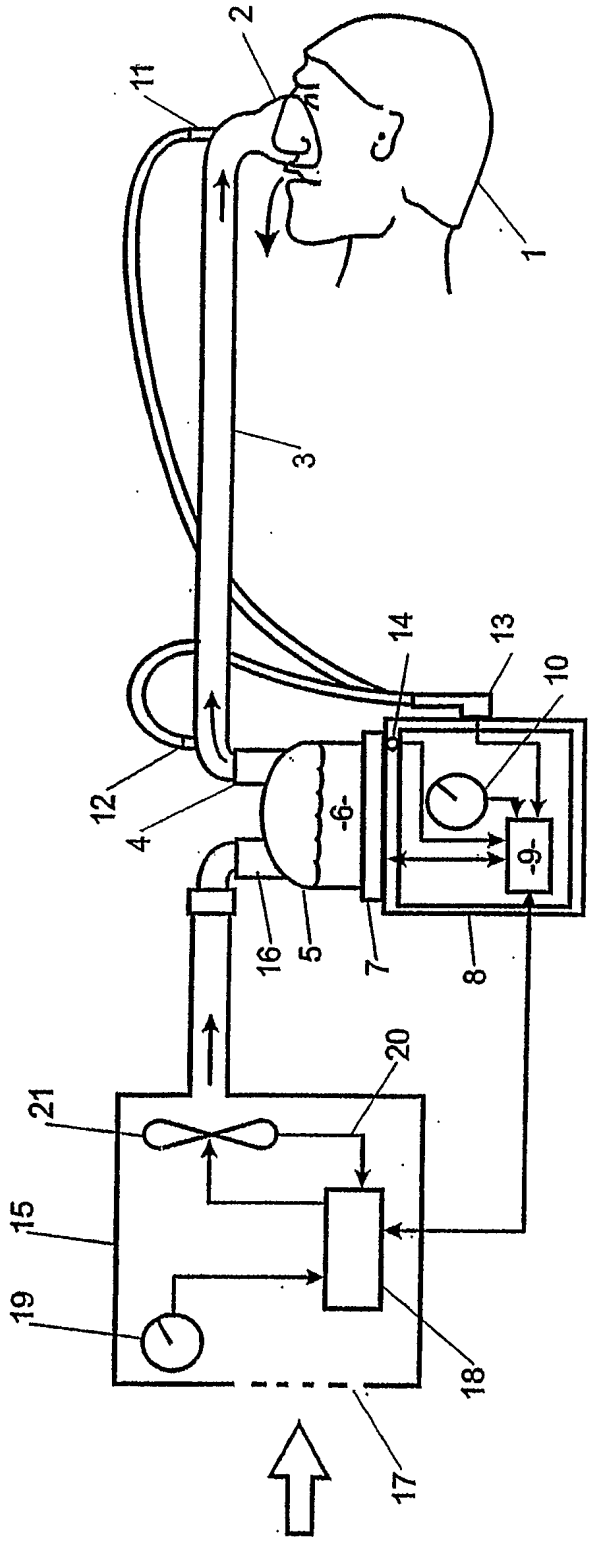

Figure 1

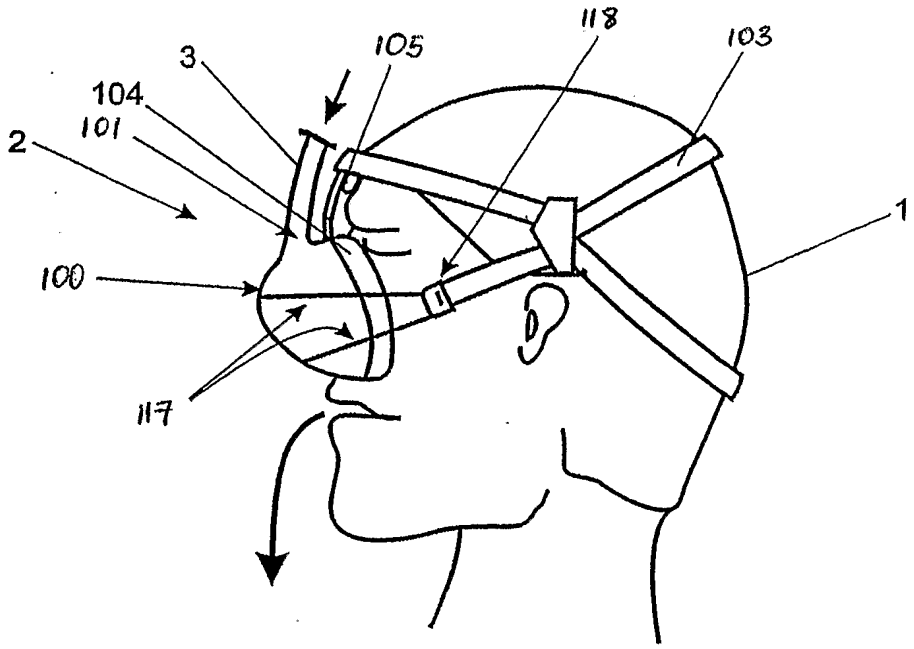

Figure 2

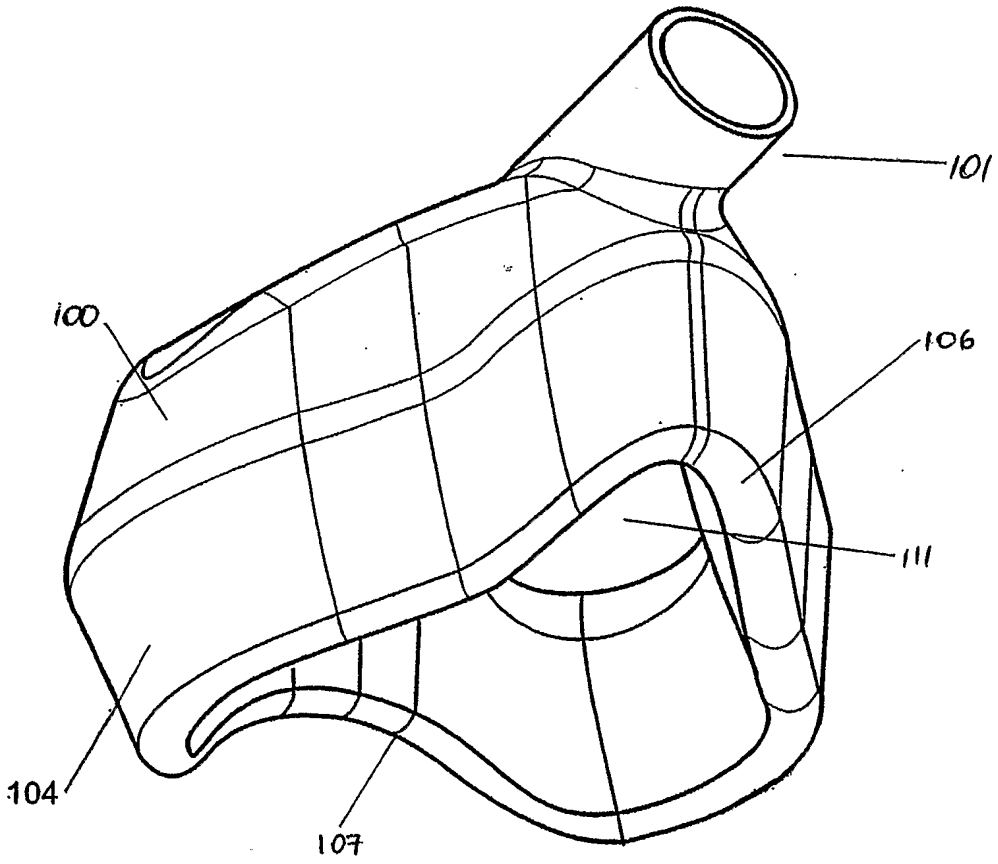

Figure 3

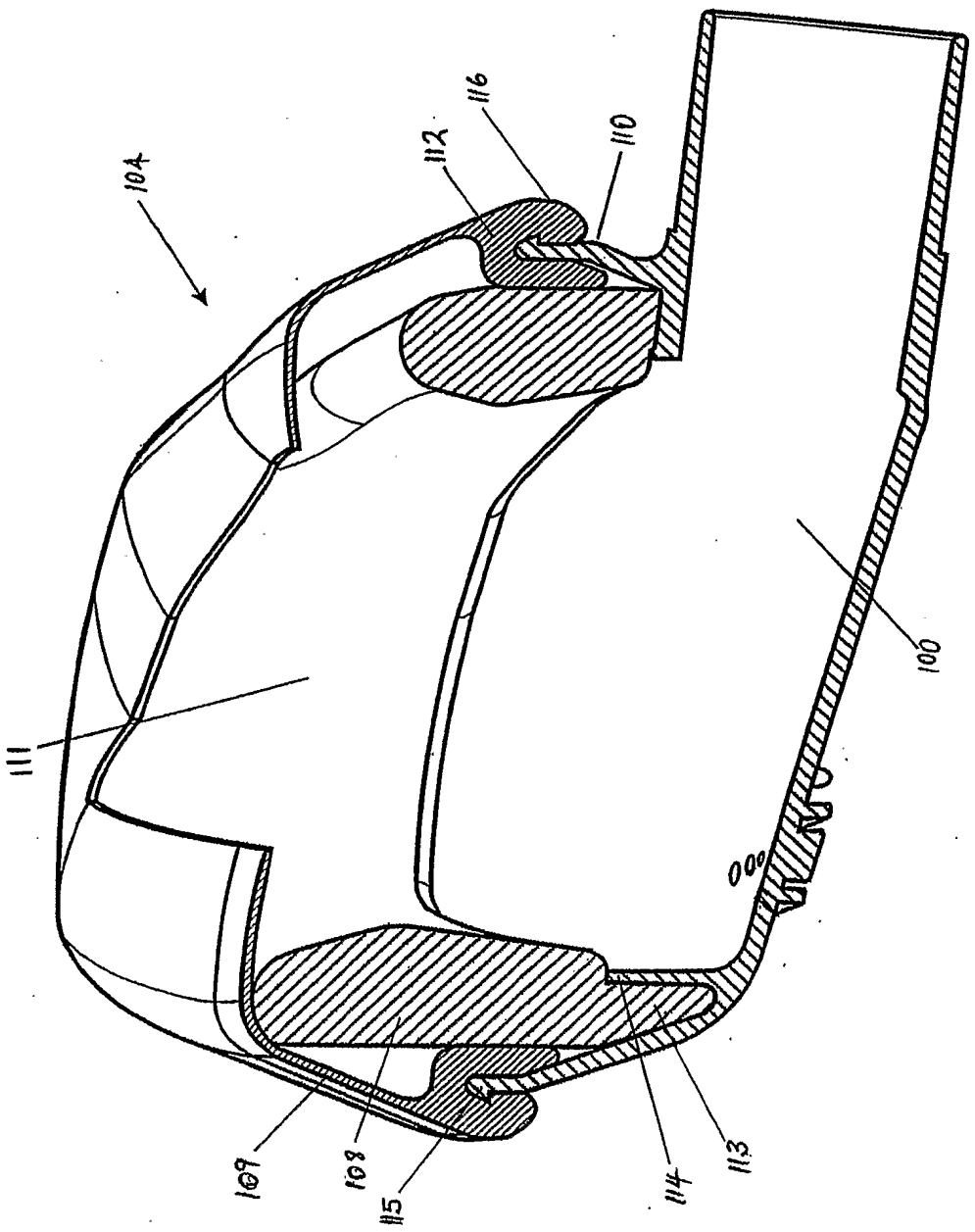

Figure 4

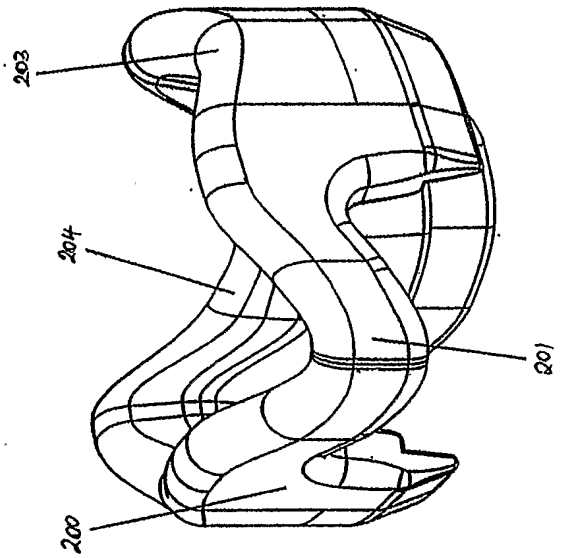

Figure 6

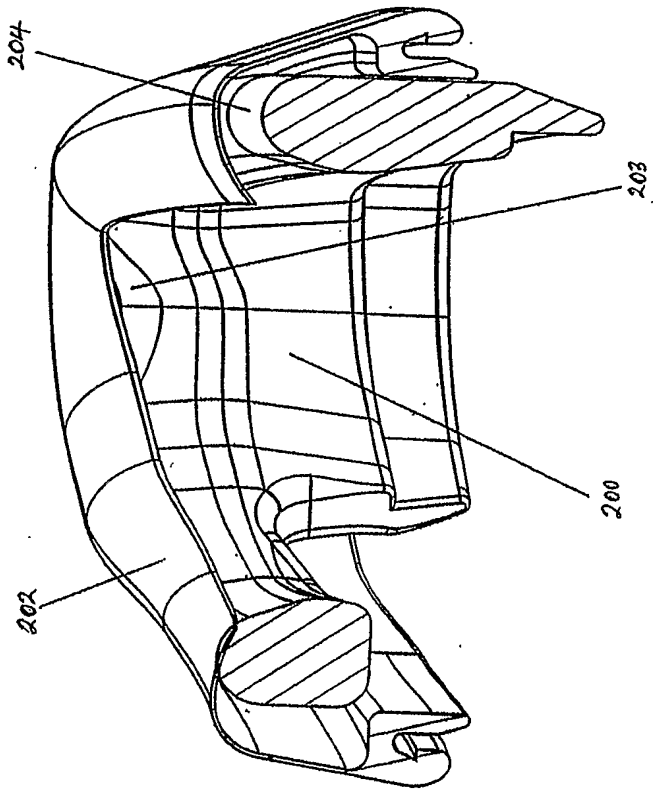

Figure 5

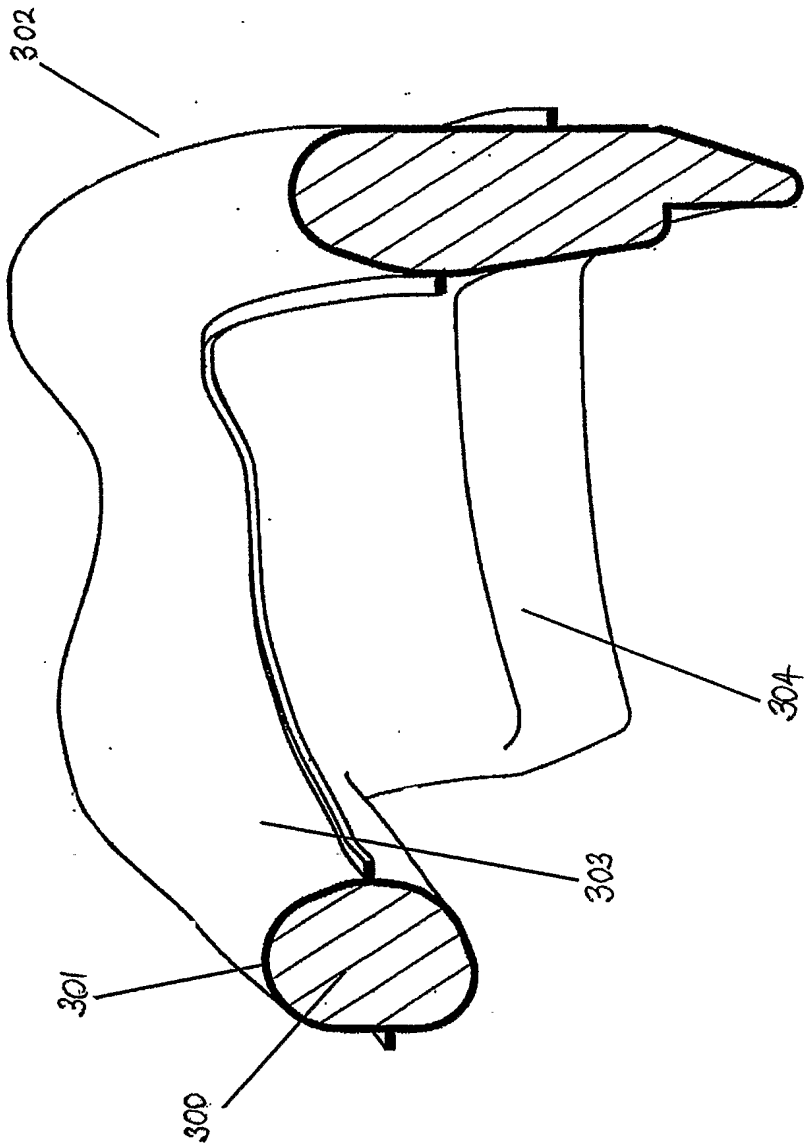

Figure 7

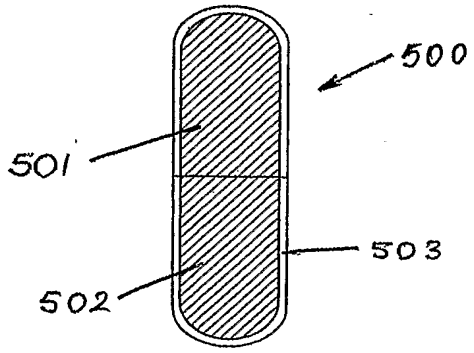

Figure 8

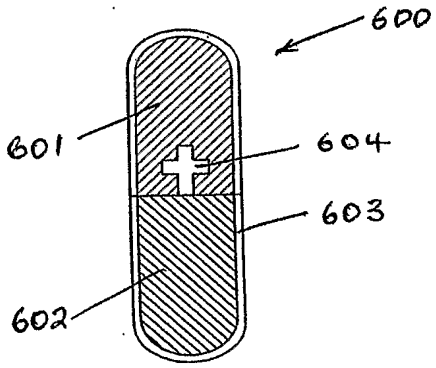

Figure 9

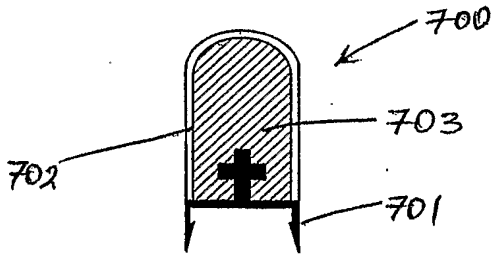

Figure 10

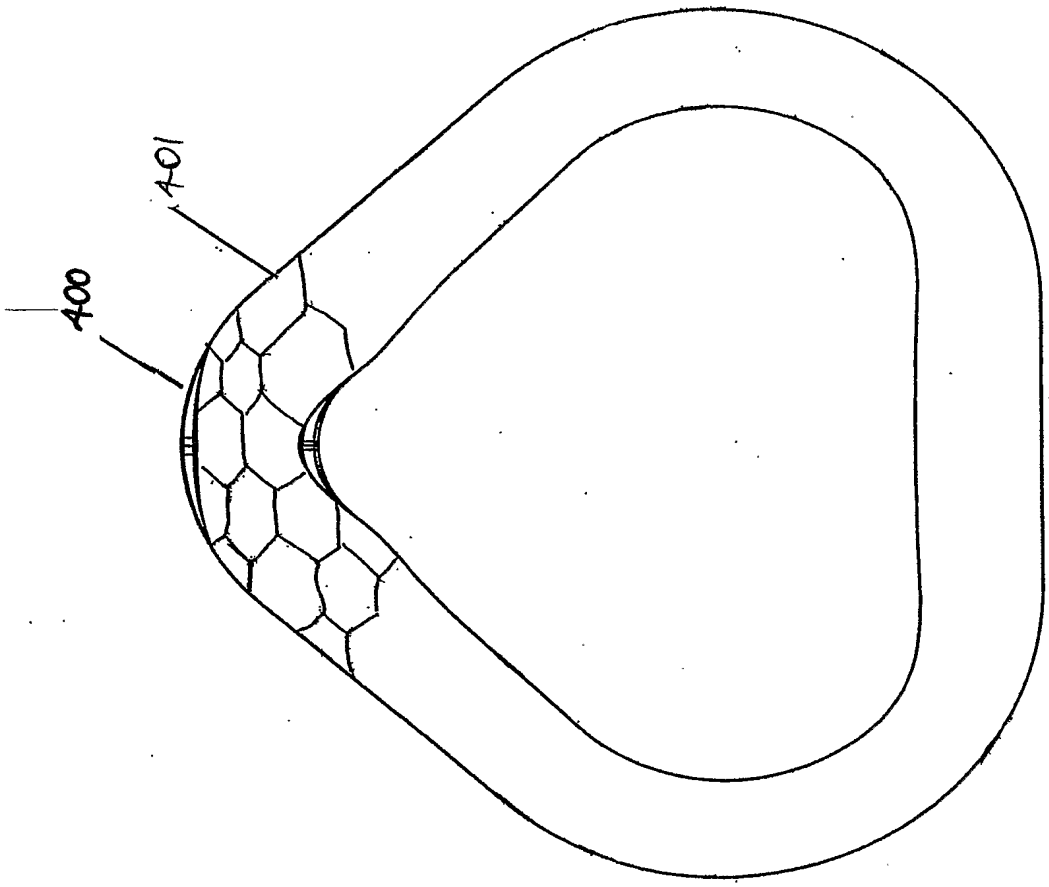

Figure 11

INTERNATIONAL SEARCH REPORT

International application No.
PCT/NZ2004/000315

A. CLASSIFICATION OF SUBJECT MATTER

Int. Cl. [7]: A61M 16/00, 16/06

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)
DWPI: IPC A61M 16/-; A62B; A61L & keywords: (patient, interface, mask, nozzle, cushion, layer, pad, cover, lining, layer, liner, outer, mould, detach, separate, remove, release, replace, void, gap, cell, space, honeycomb, cavity, adjacent, adjoin, neighbour+) and similar terms.

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X A	US 2003/0196658 A1 (GING ET AL) 23 October 2003 See Paragraphs [0168] – [0194] and figures 24a – 25i] See Paragraphs [0197] – [0223]	1-7 8-10
X	WO 1998/004310 A1 (RESMED LIMITED) 5 February 1998 Whole document	1-7
X	EP 1258266 A1 (TIARA MEDICAL SYSTEMS INC) 20 November 2002 Whole document	1-7

[X] Further documents are listed in the continuation of Box C [X] See patent family annex

* Special categories of cited documents:

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"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
8 March 2005	14 MAR 2005
Name and mailing address of the ISA/AU AUSTRALIAN PATENT OFFICE PO BOX 200, WODEN ACT 2606, AUSTRALIA E-mail address: pct@ipaustralia.gov.au Facsimile No. (02) 6285 3929	Authorized officer **KAREN VIOLANTE** Telephone No : (02) 6283 7933

INTERNATIONAL SEARCH REPORT

International application No.
PCT/NZ2004/000315

C (Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	EP 0427474 A2 (SMITHS INDUSTRIES MEDICAL SYSTEMS INC) 15 May 1991 Whole document	1-7
X	US 5441046 A (STARR ET AL) 15 August 1995 Whole document	1-7
X	WO 2001/097893 A1 (RESMED LTD) 27 December 2001 Whole document	1-7
P,X	WO 2004/007010 A1 (FISHER & PAYKEL HEALTHCARE LIMITED) 22 January 2004 Whole document	1-7
A	US 2001/0020474 A1 (HECKER ET AL) 13 September 2001 Whole document	1-7
A	DE 29923141 U1 (MPV-TRUMA GESELLSCHAFT FUR MEDIZINTECHNISCHE PRODUKTE MBH) 30 March 2000 Whole document	8-10
A	US 2002/018613 A1 (GUNARATNAM et al) 15 August 2002 Whole document	8-10
A	WO 2001/095965 A1 (FISHER & PAYKEL LIMITED) 20 December 2001 Whole document	8-10
A	US 2003/0075180 A1 (RAJE et al) 24 April 2003 Whole document	8-10
A	US 5603317 A (FARMER) 18 February 1997 Whole document	8-16
A	WO 2000/024954 A1 (MINNESOTA MINING AND MANUFACTURING COMPANY) 4 May 2000 Whole document	11-16

INTERNATIONAL SEARCH REPORT

International application No.
PCT/NZ2004/000315

C (Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US 2003/0150791 A1 (CHO ET AL) 14 August 2003 Whole document	11-16
A	US 5094236 A (TAYEBI) 10 March 1992 Whole document	11-16

INTERNATIONAL SEARCH REPORT

International application No.
PCT/NZ2004/000315

Box No. II Observations where certain claims were found unsearchable (Continuation of item 2 of first sheet)

This international search report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☐ Claims Nos.:
because they relate to subject matter not required to be searched by this Authority, namely:

2. ☐ Claims Nos.:
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:

3. ☐ Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a)

Box No. III Observations where unity of invention is lacking (Continuation of item 3 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

See attached sheet

1. ☒ As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims.
2. ☐ As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.
3. ☐ As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:
4. ☐ No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

☐ The additional search fees were accompanied by the applicant's protest.

☒ No protest accompanied the payment of additional search fees.

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Supplemental Box
(To be used when the space in any of Boxes I to VIII is not sufficient)

Continuation of Box No: III

The international application does not comply with the requirements of unity of invention because it does not relate to one invention or to a group of inventions so linked as to form a single general inventive concept. In coming to this conclusion the International Searching Authority has found that there are different inventions as follows:

1. Claims 1-7 are directed to a cushion for a patient interface. It is considered that the cushion cover and the cushion body being of the same elemental material comprise a first "special technical feature".

2. Claims 8-10 are directed to a cushion for a patient interface. It is considered that the cushion body being detachable from the outer sheath and the patient interface comprises a second "special technical feature".

3. Claims 11-14 are directed to a mask. It is considered that the plurality of adjacent voids comprises a third "special technical feature".

Since the above mentioned groups of claims do not share any of the technical features identified, a "technical relationship" between the inventions, as defined in PCT rule 13.2 does not exist. Accordingly the international application does not relate to one invention or to a single inventive concept, a priori.

It is considered that search and examination for the second and the third inventions will require more than a little additional search and examination effort over that for the first invention, and therefore additional search fees are warranted.

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No.
PCT/NZ2004/000315

This Annex lists the known "A" publication level patent family members relating to the patent documents cited in the above-mentioned international search report. The Australian Patent Office is in no way liable for these particulars which are merely given for the purpose of information.

Patent Document Cited in Search Report		Patent Family Member					
US	2003196658	AU	2003203830	AU	2003203832	AU	2003203833
		AU	2003203835	AU	2003203836	EP	1356841
		EP	1356842	EP	1356843	EP	1356844
		EP	1360971	JP	2004000570	JP	2004000571
		JP	2004000572	JP	2004000573	JP	2004000574
		US	2003196655	US	2003196656	US	2003196657
		US	2003196662	WO	2003/090827		
WO	1998/004310	AU	12454/97	AU	14892/00	AU	16355/00
		AU	16811/02	AU	26505/00	AU	34293/97
		AU	42476/99	AU	49012/00	AU	52005/00
		AU	52007/00	AU	52691/00	AU	61522/01
		CA	2261790	CA	2298129	CA	2470671
		EP	0956069	EP	1027905	EP	1187647
		EP	1187648	EP	1187649	EP	1187650
		EP	1479406	JP	2000279520	JP	2004041779
		NZ	513052	NZ	526165	NZ	526168
		US	6112746	US	6357441	US	6374826
		US	6412487	US	6428231	US	6439230
		US	6491034	US	6513526	US	6532961
		US	6561710	US	6581602	US	6585441
		US	6634358	US	6691707	US	6701927
		US	6796308	US	2002005198	US	2002005200
		US	2002023649	US	2002023650	US	2002029781
		US	2002074001	US	2002083948	US	2002096176
		US	2002104540	US	2002108613	US	2002153012
		US	2002157672	US	2002174867	US	2002174868
		US	2003034034	US	2004025881	US	2004086319
		US	2004094159	US	2004099272	US	2004134497
		US	2005022818	WO	2000/078381	WO	2000/078382
		WO	2000/078383	WO	2000/078384	WO	2001/034406
		WO	2001/084979				
EP	1258266	BR	0201863	CA	2386686	US	2003019495

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No.
PCT/NZ2004/000315

EP	0427474	CA	2019533	EP	0427473	GB	2237746
		GB	2237811				
US	5441046		NONE				
WO	2001/097893	AU	67133/01	EP	1292351	US	6772760
		US	2002029780	US	2003089372	US	2004144386
WO	2004/007010		NONE				
US	2001020474	DE	10002571	EP	1118346		
DE	29923141	AU	45035/99	EP	1087811	WO	9965554
US	2002018613	US	6594058	US	6829399	US	2001028756
		US	2001033708	US	2002003920	WO	0165302
		WO	0165303	WO	0167161	WO	0167162
WO	0195965	AU	15432/02	AU	51876/01	AU	51877/01
		AU	67947/01	BR	0212453	CA	2350351
		CA	2350356	CA	2370995	CA	2407118
		CA	2413938	CA	2457277	EP	1163923
		EP	1163924	EP	1289590	EP	1302212
		EP	1306098	EP	1425060	JP	2002028240
		JP	2002095751	NZ	508219	NZ	514972
		US	6615834	US	6662803	US	6701926
		US	6789541	US	6832610	US	2002005201
		US	2002014241	US	2003000533	US	2003062048
		US	2003066531	US	2003089373	US	2003111080
		US	2003154978	US	2003196659	US	2003217746
		US	2004035428	US	2004065327	US	2004244800
		US	2004244804	US	2004255950	WO	03022341
		WO	03030978				
US	2003075180	EP	1334742	JP	2003175106	US	6823869
		US	2004112384	US	2004112385	US	2004112387
		US	2004118406	WO	2004022144	WO	2004022145
		WO	2004022146	WO	2004022147		
US	5603317						
WO	0024954	AU	29743/99	BR	9914915	CA	2346795
		CN	1342229	EP	1127183	NO	20012037
		NZ	511273	PL	348662	US	6139308
		US	6492286				
US	2003150791	AU	2003207804	CA	2475800	EP	1471991

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No.
PCT/NZ2004/000315

		US	2004154972	WO	03068373		
US	5094236	US	4856508	US	4945907	US	5080094

Due to data integration issues this family listing may not include 10 digit Australian applications filed since May 2001.

END OF ANNEX